K102368

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510(K) Summary

Date Prepared [21CFR 807.92(a)(1)]
8/19/2010

Submitter's Information [21CFR 807.92(a)(1)]

Mr. Jonathan Achenbach
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SEP 07 2010

The establishment registration number for Ellman International is 2428235

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name

Non-Ablative Wrinkle Treatment Handpiece

Device common, usual or Classification Names

Device: Electrosurgical, cutting & coagulation & accessories

Regulation Description: Electro surgical cutting and coagulation device and accessories

Class

Classification: Class II
Product Code: GEI

Device Description [21 CFR 807.92(a)(4)]

The purpose of this submission is to modify the **Cleaning / Disinfection methods** of the Non-Ablative Wrinkle Treatment Handpiece cleared as Ellman Non-Ablative Wrinkle Treatment Handpiece under K101967. The device is identical to the device cleared under K101967 Ellman International Non-Ablative Wrinkle Treatment Handpiece except for the modified Cleaning/Disinfection method.

The proposed method is:

Method:
Disinfect Handpiece and Cable prior to and after each procedure by wiping exterior surfaces with a lint free cloth soaked in liquid solution containing 70% Isopropyl Alcohol. Ensure surface

remains wet for at least 5 minutes. An additional application of 70% Isopropyl Alcohol should be applied if the surface appears dry during the 5 minute period.

Ellman International has presented a successfully executed test protocol as part of this submission to demonstrate that the methods described above achieve an adequate log reduction of inoculated challenge organisms on the test devices.

Further to this, Ellman International has presented substantial evidence to support the claims made in method above to provide an effective alternate cleaning and disinfection instruction to the existing instructions for use.

Intended Use [21 CFR 807.92(a)(5)]

The device has the following "Indications For Use"

- Non-ablative treatment of mild to moderate facial wrinkles and rhytides for skin phototypes I-IV

Technological Characteristics [21 CFR 807.92(a)(6)]

Ellman International maintains that the subject device is identical to the predicate device except for the modified cleaning and disinfection method.

Labels, Labeling [21 CFR XXXX]

Per section "Product Labels"

Performance Data [21 CFR 807.92(b)(1)]

As defined in **SGS Protocol # 09A1006547** and demonstrated in **SGS Report# 09A1006548**

Predicate Devices [21 CFR 807.92(a)(3)(1)]

The device is substantially equivalent to the Non-Ablative Wrinkle Treatment Handpiece cleared as Ellman Non-Ablative Wrinkle Treatment Handpiece under K101967.

Consideration for Special 510(k) Status

In accordance with the FDA guidance document: The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications - Final Guidance Attachment 2, Ellman Internal maintains that this change in the cleaning and disinfection method is a "Device Modification" and therefore requests that the FDA considers it as such.

As there are no technological, structural, design or intended use changes for the subject device, Ellman International believes that no further data or clinical study is required to support the position that the device is safe and effective to use with the changes delineated in the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ellman International, Inc.
% Mr. Jonathan Achenbach
Sr. Director R & D, Clinical
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3333 Royal Avenue
Oceanside, New York 11572

SEP 07 2010

Re: K102368
Trade/Device Name: Non-Ablative Wrinkle Treatment Handpiece
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 19, 2010
Received: August 20, 2010

Dear Mr. Achenbach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

"INDICATIONS FOR USE"
Statement

510(k) Number (if known): K102368

SEP 07 2010

Device Name: Non-Ablative Wrinkle Treatment Handpiece

The Device has the following "Indications for Use":

Non-ablative treatment of mild to moderate facial wrinkles and rhytides for skin phototypes I-IV

Prescription Use ___X___ OR Over-The Counter Use_____
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102368